ncasi

NATIONAL COUNCIL FOR AIR AND STREAM IMPROVEMENT, INC.
West Coast Regional Center
***Mailing address*: PO Box 458, Corvallis OR 97339**
***Street address*: 720 SW Fourth Street, Corvallis OR 97333**
Phone: (541)752-8801 Fax: (541)752-8806

Dr. Jeff Louch
Principal Research Scientist
JLouch@wcrc-ncasi.org

August 11, 2006

Pete Kmet
Washington State Department of Ecology
Toxics Cleanup Program
PO Box 47600
Olympia, Washington 98504-7600

Dear Mr. Kmet:

The National Council for Air and Stream Improvement, Inc. (NCASI) is an independent, non-profit membership organization that provides technical support to the forest products industry on environmental issues. An important part of our mission is to ensure that regulatory decision making is based on sound science. In this capacity, NCASI has reviewed the June 2006 proposed revisions to Section 708 of the Model Toxics Control Act (MTCA, Chapter 173-340 WAC). That document proposes that all dioxin congeners be considered as a single chemical or substance when assessing compliance with cleanup levels or otherwise assessing risk. The mechanism proposed for accomplishing this is based on the use of Toxicity Equivalency Factors (TEFs). The proposed revision also gives analogous language for all carcinogenic polycyclic aromatic hydrocarbons (cPAH) and multiple polychlorinated biphenyl (PCB) congeners.

Although the specific language for which Ecology has solicited comment is fairly limited, it is essentially impossible to provide informed comment without revisiting some of the broader assumptions made by Ecology in the rule as a whole. Specifically, it is necessary to revisit how Ecology has chosen to use TEFs in the estimation of risk and/or the calculation of cleanup levels. Although there are significant debates over many aspects of the TEF paradigm, the use of TEFs as a means to assess cumulative toxicity via Total Toxicity Equivalents (TEQs) is generally accepted within the scientific community as long as some specific criteria are met. NCASI believes that both the original MTCA rule and the proposed revision ignore some of these criteria, and thus attempt to apply the TEF/TEQ construct inappropriately. Overall, our concerns can be summarized:

- the TEF/TEQ construct as applied in the MTCA rule is inconsistent with sound science
- without chemical-specific modeling of cross-media transfer and thus exposure, TEQs do not provide an accurate measure of risk
- the misuse of the TEF/TEQ construct results in overestimation of the risks associated with both individual chemicals and mixtures of chemicals found, e.g., in soils

The "Technical Comment" attachment to this letter provides additional detail addressing these concerns.

Overall, NCASI's primary concern is that Ecology has used the World Heath Organization (WHO) TEFs to back-calculate cleanup levels from risk levels without explicitly accounting for differences in various exposure pathways. This is clearly incorrect from a scientific perspective. To rectify this, Ecology must make clear that all calculations of cleanup levels should use chemical/congener-specific parameters and, based on a review of the literature (attached), Ecology must modify the default gastrointestinal absorption factor (AB1) used to model absorption of dioxins from ingested soil from the current value of 1.0 to the more scientifically credible value of 0.3 for tetra- through hexachlorinated dioxins, and 0.1 for hepta- through octachlorinated dioxins. NCASI recognizes that the rule allows individuals to petition to use alternate values for AB1, but suggests that setting the default value to 1.0 essentially penalizes responsible parties that do not have the resources to fully research the science behind these numbers.

Note that even though the attached focuses on dioxins, the general issues raised are also relevant to both cPAHs and PCBs.

Please do not hesitate to contact me if you have any questions concerning these comments.

Sincerely,

Jeff Louch, PhD
Principal Research Scientist

Attachment

pc: Steve Stratton, NCASI
Paul Wiegand, NCASI
Llewellyn Matthews, NWPPA

TECHNICAL COMMENT

The TEF/TEQ Paradigm is Inappropriately Applied to Abiotic Media - The World Health Organization (WHO) has recently completed a re-evaluation of TEFs for dioxins and dioxin-like compounds (DLC). As part of this, WHO has commented (Van den Berg et al. 2006) that the current TEF/TEQ construct is relevant to risk incurred from ingestion of foodstuffs (e.g., breast milk), but that using it for characterizing risks associated with exposures to abiotic media containing dioxins is inappropriate. Thus, the following statement (Van den Berg et al. 2006):

> "For example, direct application of these WHO TEFs for assessment of OCDD and OCDF present in soil, sediment or fly ash would lead to inaccurate assessment of the potential toxic potency of the matrix."

All of this reflects the reality that TEFs themselves are derived based to a large extent on administered dioxin concentrations (i.e., concentrations in ingested food), and not the final dose actually accumulated by an organism. Thus, the TEFs are inherently specific to one route of exposure: the ingestion of relatively fatty foods (e.g., oils and milk). Since the relative amount of a given dioxin congener actually taken up (accumulated) by an organism depends on the nature of the ingested material, the use of these WHO TEFs to assess the risk associated with other routes of exposure (e.g., ingestion of soil) is scientifically incorrect unless some accounting for these different routes of exposure is made.

It is Never Correct to "Back-Calculate" Cleanup Levels from a Risk Level without Accounting for Exposure Pathway on a Chemical/Congener-Specific Basis - The MCTA rule often reads as if Ecology considers concentration to be equivalent to risk in that it specifies the back-calculation of cleanup levels from risk levels without fully accounting for exposure. This is scientifically incorrect in any situation as it ignores the fact that the risk posed to an organism by a chemical in, e.g., soil, is mediated by the relative amount of the chemical actually taken up (accumulated) by the organism; i.e., the risk is proportional to the actual dose received, not the original concentration in the external media.

When considering media such as foodstuff, soil, air, or water there must be some transfer of chemical into an organism before there can be any risk to the organism; i.e., there must be some cross-media transfer. Some of the factors that must be accounted for in determining the ultimate dose received by a human from, e.g., ingesting soil, include the bioavailability of the chemical as it is incorporated into the soil matrix, the efficiency with which the chemical is taken up by the body (gastrointestinal absorption) once "desorbed" from the soil, and any metabolism of the chemical once in the body. If any of these factors are ignored the risk associated with a specific concentration of a specific chemical in soil (in this case) will essentially always be overstated.

Congener-Specific Parameters Must be used in all Calculations – The new language for Section 173-340-708(g)(ii) included in the June 2006 (proposed) revisions to the MTCA rule is an acknowledgment of the issues noted above. The new (proposed) Section 173-340-708(g)(ii) states:

> "When using toxicity equivalency factors, use the congener and carcinogenic PAH-specific properties when modeling the behavior of these hazardous substances to determine the concentration in the receiving medium."

This is scientifically correct and NCASI believes this exact wording should apply universally (irrespective of the use of TEFs), and that all tables giving parameters for use in either forward-calculation of risk or back-calculation of cleanup levels should be footnoted to specify the use of chemical-specific values when available; e.g., Tables 740-2 and 745-1 should be footnoted to make clear that the use of chemical/congener-specific gastrointestinal absorption factors (AB1) is allowed if not encouraged.

With these points in mind, the only way to correctly characterize risk (e.g., to a human) associated with a mixture of chemicals is to determine the risk posed by each chemical by itself, and to then sum these risks. In the specific case of soil ingestion by any animal, this approach requires that the amount of each chemical actually accumulated be determined based on chemical-specific properties. As noted by WHO (Van den Berg et al. 2006), expressing the original soil concentrations of the individual chemicals/congeners in TEQ units does not obviate the need to adjust for differential uptake, except perhaps in the very specific case of ingestion of specific (relatively fatty) foods.

The Assumption of a Gastrointestinal Absorption Factor (AB1) of 1 for all Dioxins in all Media is Scientifically Incorrect – As noted above, the relative amount of a given chemical in a specific ingested material actually taken up (accumulated) by an organism depends on the nature of the ingested material and the chemical itself. For any given chemical, the gastrointestinal absorption of truly "free" chemical (i.e., chemical that is truly bioavailable) would be expected to be constant (considering a specific organism), but the relative amount of a chemical in an ingested material that is actually bioavailable will vary with the material. Thus, overall, both bioavailability and gastrointestinal absorption must be considered on a molecule-specific basis when predicting the actual dose received by an organism from ingesting a specific material. However, the procedures specified by Ecology for calculating cleanup levels account for gastrointestinal absorption only (e.g., Equation 740-2 includes a term, AB1, for gastrointestinal absorption, but not a term for bioavailability). Although not scientifically correct in the strictest sense, this can be a useful approximation if the AB1 values are derived based on concentrations in the ingested material; i.e., if absorption efficiency is expressed relative to total concentration in the ingested material.

The literature contains multiple reports of studies characterizing gastrointestinal absorption as a function of concentration in ingested material which would be appropriate for use, e.g., in Equation 740-2. As reported by EPA (USEPA 1985, 2003), appropriate AB1 values for 2,3,7,8-TCDD derived from rat feeding studies were from 50% to 60% (i.e., 0.5 to 0.6) when the chemical was administered in a mixed diet. When the chemical was administered by gavage in corn oil, AB1 values were from 70% to 86%, and when administered by gavage in 50% ethanol they ranged from 37% to 52%. When 2,3,7,8-TCDD was administered (gavage) in aqueous soil mixtures absorption was observed to drop by approximately 50% relative to that observed with ethanol (Poiger and Schlatter 1980), and the extent of this decrease was correlated with the

length of time the 2,3,7,8-TCDD had been left to equilibrate with the soil. Studies (Shu et al. 1988) with rats using soils from Times Beach resulted in an estimated AB1 value for 2,3,7,8-TCDD of 43 ± 4% (Shu et al. 1988).

Note that since these studies are all specific to 2,3,7,8-TCDD and uptake by rats, the variability in uptake reflects the impact of differential bioavailability from the different materials administered.

Similar observations have been reported from studies performed with guinea pigs. For example, Umbreit et al. (1986) administered (by gavage) two soils to guinea pigs as 10% suspensions in 5% gum acadia, and concluded that < 0.5% of the administered 2,3,7,8-TCDD in one soil and approximately 21% in the second soil was bioavailable. Additional guinea pig studies performed using soils from Times Beach gave a value for 2,3,7,8-TCDD of 30% (Wendling et al. 1987).

Per the above, all studies performed with animals clearly show that uptake of dioxins from soils is considerably reduced relative to uptake from, e.g., corn oil. Thus, even though control studies with humans are limited (and none directly address uptake from soils), evidence that absorption by humans from foodstuffs is high does not by itself allow assumption that absorption from soils is also high. In fact, this assumption is contrary to the limited human data that are available. For example, Dahl et al. (1995) have reported data showing high absorption (>95%) of tetra- through hexachlorinated dioxins from breast milk , but the work of Schlummer et al. (1998) showed a *maximum* net absorption of multiple dioxin congeners from mixed foodstuffs of 63%. Based on the results from animal studies, absorption from soil would be expected to be less than observed from mixed food.

As part of a review of the toxicokinetics of dioxins, Van den Berg et al. (1994) observed that gastrointestinal absorption of the different dioxin congeners is “variable, incomplete, vehicle-dependent, and congener-specific.” This same review notes that the data suggests there “are no interspecies differences in the GI absorption of these compounds,” meaning that the data noted above are relevant to ingestion of soils by humans. Finally, these authors suggest that oral bioavailability for tetra- to hexachlorinated dioxin congeners in the range of 25% to 50% may in fact be overstated for soils having high organic content, and that consideration of molecular size makes an oral bioavailability of 10% appropriate for hepta- and octachlorinated dioxins. Consistent with this, EPA assumes that 30% of dioxin ingested with soil is absorbed by humans (USEPA 2003).

Based on the above, when considering the ingestion of soil the most scientifically defensible default value of AB1 for tetra- through hexachlorinated dioxin congeners is 0.3, and 0.1 for hepta- through octachlorinated dioxin congeners.

REFERENCES

Dahl, P., Lindstrom, G., Wiberg, K, and Rappe, C. 1995. Absorption of polychlorinated biphenyls, dibenzo-p-dioxins and dibenzofurans by breast-fed infants. *Chemosphere*. 30(12):2297-2306.

Poiger, H. and Schlatter, C. 1980. Influence of solvents and adsorbents on dermal and intestinal absorption of TCDD. *Food and Cosmetics Toxicology* 18:477.

Schlummer, M., Moser, A.G., and McLachlan, M.S. 1998. Digestive tract absorption of PCDD/Fs, PCBs, and HCB in humans: Mass balance and mechanistic considerations. *Toxicology and Applied Pharmacology* 152:128-137.

Shu, H., Paustenbach, D., Murray, F.J., Marple, L., Brunck, B., Dei Rossi, D., and Teitelbaum, P. 1988. Bioavailability of soil-bound TCDD: oral bioavailability in the rat. *Fundamental and Applied Toxicology* 10:648-654.

Umbreit, T.H., Hesse, E.J., and Gallo, M.A. 1986. Bioavailability of dioxin in soil from a 2,4,5-T manufacturing site. *Science* 232:497-499.

United States Environmental Protection Agency (USEPA). 1985. Health assessment document for polychlorinated dibenzo-p-dioxins. EPA/600/8-84/014F. Washington, DC: United States Environmental Protection Agency.

United States Environmental Protection Agency (USEPA). 2003. Exposure and human health reassessment of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) and related compounds National Academy of Sciences (NAS) review draft. Available online at http://www.epa.gov/ncea/pdfs/dioxin/nas-review/ (August 11, 2006).

Van den Berg, M., De Jongh, J., Poiger, H., and Olson, J.R. 1994. The toxicokinetics and metabolism of polychlorinated dibenzo-p-dioxins (PCDDs) and dibenzofurans (PCDFs) and their relevance for toxicology. *Critical Reviews in Toxicology* 24(1):1-74.

Van den Berg et al. 2006. The 2005 World Health Organization re-evaluation of human and mammalian toxic equivalency factors for dioxins and dioxin-like compounds. Available online at http://toxsci.oxfordjournals.org/cgi/reprint/kfl055v1 (August 11, 2006) or http://toxsci.oxfordjournals.org/cgi/content/abstract/kfl055v1 (August 11, 2006).

Wendling, J., Hileman, F., Orth, R., Wilson, J., Umbreit, T., Hesse, E., and Gallo, M. 1987. An analytical assessment of the bioavailability of dioxin contaminated soils to animals. In *Proceedings, Seventh International Symposium on Chlorinated Dioxins and Related Compounds*, October 4-9, 1987, Las Vegas, Nevada. (Abstract).